



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/00, F16L 11/00	A1	(11) International Publication Number: WO 95/13110 (43) International Publication Date: 18 May 1995 (18.05.95)
(21) International Application Number: PCT/US94/13014 (22) International Filing Date: 14 November 1994 (14.11.94) (30) Priority Data: 08/151,320 12 November 1993 (12.11.93) US (71) Applicant: MICRO INTERVENTIONAL SYSTEMS [US/US]; 5113 Fairglen Drive, Plano, TX 75093 (US). (72) Inventors: JARACZEWSKI, Richard, S.; 10040 Tesla Road, Livermore, CA 94550 (US). McQURK, Erin; 5113 Fairglen Drive, Plano, TX 75093 (US). (74) Agents: HEINES, M., Henry et al.; Townsend and Townsend Khourie and Crew, 20th floor, Steuart Street Tower, One Market Plaza, San Francisco, CA 94105-1492 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>
(54) Title: SMALL DIAMETER, HIGH TORQUE CATHETER <div style="text-align: center; margin: 20px 0;"> </div> <p>(57) Abstract</p> <p>A catheter (10) comprises an inner tubular member (30), a braided reinforcement layer (32), and a soft outer layer (34). The inner tubular member (30) extends from a proximal end of the catheter (10) to a first distal location (18). The braided reinforcement layer (32) extends from the proximal end of the catheter to a second distal location (22) which is usually located proximally from the first distal location (18). The soft outer layer (34) extends from the proximal end of the catheter to a third distal location which is usually located distally of the first distal location (18). In this way, a catheter (10) having a shaft region (16), a transition region (20), and a distal region (26), each with different strength and flexibility characteristics, can be obtained. Such catheter constructions are particularly useful for very small diameter access catheters.</p>		

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SMALL DIAMETER, HIGH TORQUE CATHETERBACKGROUND OF THE INVENTION1. Field of the Invention

5 The present invention relates generally to medical catheters and methods for their fabrication. More particularly, the present relates to the construction of small diameter, braid-reinforced catheters having controlled flexibility and a soft distal tip which are particularly useful for intercranial
10 selective catheterization.

 Medical catheters exist for a wide variety of purposes, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like.
15 Catheters for each of these purposes can be introduced to numerous target sites within a patient's body by guiding the catheter through the vascular system, and a wide variety of specific catheter designs have been proposed for different uses.

20 Of particular interest to the present invention, small diameter tubular access catheters are presently being used for diagnostic and interventional neurological techniques, such as the imaging and treatment of aneurysms, tumors, arteriovenous
25 malformations/fistulas, and the like. The neurological vasculature places a number of requirements on the catheters which are to be employed. The primary requirement is size. The blood vessels in the brain are frequently as small as several millimeters, or less,
30 requiring that the catheters have an outside diameter as small as one French (1F; 0.33 millimeters). In addition to small size, the brain vasculature is highly tortuous, requiring that neurological catheters be very flexible, particularly at their distal ends, to pass through the
35 regions of tortuosity. Difficulties in endovascular positioning, however, make it desirable to impart high tensile and column strength over at least the proximal

portion of the catheter. Additionally, the blood vessels of the brain are relatively fragile, so it is desirable that the catheter have a soft, non-traumatic exterior to prevent injury.

5 In an effort to meet at least some of these requirements, the small-diameter, variable flexibility catheters, such as Tracker® infusion catheters available from Target Therapeutics, Fremont, California, have been developed. Although generally successful, the Tracker®
10 catheters suffer from certain deficiencies. In particular, to achieve high flexibility, tensile strength and catheter wall integrity have been compromised. The Tracker® catheters thus lack both column strength and hoop strength and have a tendency to kink and collapse
15 when passing around small diameter bends. Directability and torqueability of the Tracker® catheters is also limited, and the most flexible distal regions of the catheter are subject to rupture and perforation.

 It would therefore be desirable to provide
20 improved small diameter, flexible catheters suitable for introduction to very small blood vessels, particularly to the neurological vasculature. Such catheters should provide sufficient flexibility to permit access to the tortuous regions of the neurological vasculature, while
25 retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse. The improved catheters should also have enhanced positioning characteristics, including pushability and torqueability. Additionally, it would be desirable to have an improved
30 wall strength over a portion or all of the catheter wall to resist perforation and failure when introducing high pressure fluids and/or introducing thrombogenic coils and other devices through the catheter.

2. Description of the Background Art

35 U.S. Patent No. 4,739,768, describes a catheter consisting of an inner layer and an outer layer, where the inner layer terminates proximally of the outer layer

to form a relatively more flexible distal end.
WO91/17782 describes a catheter having a braid-reinforced
distal end with a low friction surface. WO93/02733
describes a catheter having four regions of different
5 stiffness. Braid and otherwise reinforced catheter
structures are described in U.S. Patent Nos. 3,416,531;
3,924,632; 4,425,919; 4,586,923; 4,764,324; 4,817,613;
4,899,787; 5,045,072; 5,057,092; 5,061,257; and
EP 555 088. Catheters having soft tips are described in
10 U.S. Patent Nos. 4,636,346 and 5,078,702. A torque
control catheter comprising stainless steel braid-
reinforced polyethylene is described in Catalog 1982-84
"Radiology, Cardiology and Surgery," page 16, Cook Inc.
The requirements and considerations for constructing
15 catheters and other system components for intercranial
selective catheterization are described in Rüfenacht and
Latchaw (1992) Inter. Neurorad. 2:251-268.

SUMMARY OF THE INVENTION

A catheter constructed in accordance with the
20 principles of the present invention comprises a catheter
body including an inner tubular member, a braided
reinforcement layer disposed over the inner tubular
member, and a soft outer layer formed over the braided
reinforcement layer. The flexibility of the catheter
25 body is controlled by selecting the relative lengths and
mechanical characteristics of each of these components.
The inner tubular member extends a first length with the
braided reinforcement layer usually terminating
proximally of the distal end of the inner tubular member,
30 preferably by distance in the range from about 0 cm to
10 cm, more preferably from 1 cm to 10 cm, most
preferably from 1 cm to 3 cm. The soft outer layer will
usually terminate distally of the distal end of the inner
tubular member, preferably by a distance in the range
35 from about 0 cm to 10 cm, more preferably from 1 cm to
10 cm, and most preferably from 1 cm to 3 cm. In this
way, up to three distinct regions of flexibility, tensile

strength, column strength, and hoop strength may be provided. In addition or as an alternative to terminating the layers at different locations relative to each other, flexibility, tensile strength, column
5 strength, and hoop strength may be varied by selectively controlling the mechanical characteristics of one or more of the individual layers. In particular, the pitch and other braid characteristics of the braided reinforcement layer may be varied to provide increased strength
10 properties along the proximal portions of the catheter body and increased flexibility over the distal portion of the catheter body. The use of the braided reinforcement layer in the catheters of the present invention is particularly advantageous since it provides substantial
15 tensile, column, and hoop strengths with minimum loss of flexibility.

In the exemplary embodiment, a major portion of the catheter body extending from its proximal end to the termination of the braided reinforcement area is the
20 least flexible, but has excellent torque transmission and hoop strength characteristics. The region of the catheter distal to the braid termination but proximal to the termination of the inner tubular member has enhanced flexibility while retaining adequate torqueability and
25 hoop strength to permit guiding of the catheter over a guide wire and prevent kinking and collapse of the catheter lumen. The distal-most region of the catheter comprises only the soft outer layer and possesses the greatest flexibility with the minimum torqueability and
30 hoop strength, and the catheters of the present invention are suitable for introduction to remote, tortuous regions of the brain vasculature.

In a first particular aspect of the present invention, the inner tubular member is composed of a
35 lubricious material, such as a fluorocarbon polymer, polyamide, a polyolefin, a polyimide, or the like, preferably being formed from polytetrafluoroethylene

(PTFE). The use of such materials provides a very smooth surface for introducing devices and high velocity fluids through the lumen defined by the inner tubular member. The catheter of the present invention includes only a single transition from the inner tubular member to the contiguous lumen defined by the soft outer layer which extends beyond the distal termination of the inner tubular member.

In a second preferred aspect of the present invention, the braided reinforcement layer is composed of a filament braid, preferably a stainless steel braid, which is annealed and transversely cut at its distal end to remove any protrusions, burrs, discontinuities, or the like, which may result from the termination of braiding. Such discontinuities in the braid at the distal end (or elsewhere) are unacceptable as they would expose the vasculature to trauma, even when covered by the soft outer layer. Previous catheter constructions have generally relied on covering braid terminations with a ring or other protective structure. The present invention avoids the need for any additional structure at braid termination by use of the unique annealing and cutting process, as described in more detail hereinafter.

In a third particular aspect of the present invention, the material of the soft outer layer has a hardness in the range from 30 A to 72 D, and is preferably selected from the group consisting of polyamide polyether block copolymer (Pebax®), polyurethane, silicone rubber, nylon, and the like.

In a fourth particular aspect of the present invention, a catheter body consists essentially of the inner tubular member, the braided reinforcement layer, and the soft outer layer, as described above, and is free from other structural components which would change the essential mechanical and structural characteristics of the catheter, particularly with regard to flexibility, torque transmission, and softness of the exterior. Such

catheter bodies may, however, include other components which do not affect the essential mechanical and structural characteristics, such as proximal connectors, proximal housings, radiopaque markers, and the like.

5 According to a method of the present invention, the catheters may be fabricated by providing an inner tubular member, preferably having the characteristics described above. A braid is formed over the inner
10 tubular member from the proximal end to a location spaced proximally from the distal end of the inner tubular member by a distance in the range from 0 cm to 10 cm, preferably from 1 cm to 10 cm, and more preferably from 1 cm to 3 cm. A soft outer layer is then formed over the
15 resulting assembly from its proximal end and extending distally beyond the distal end thereof by a distance in the range from 0 cm to 10 cm (when extending distally beyond the inner tubular member). The soft outer layer further defines a distal lumen which is contiguous with the lumen of the inner tubular member. Preferably, each
20 of the above-fabrication steps occurs while the inner tubular member is disposed over a mandrel which supports the inner tubular member and extends beyond the distal end of said member.

 The braid is formed from stainless steel ribbon
25 or other suitable material, typically as a one-over-one or two-over-two braid. After the braid is formed over the inner tubular member and the distal end terminated, the braid is translated distally to extend beyond the mandrel. The braid is then annealed, typically by
30 heating, and the annealed braid filaments cut transversely to form a square-cut end which is free from protrusions, burrs and other discontinuities. The braid is then translated proximally back over the inner tubular member to the desired position space proximally from the
35 distal end thereof. The soft outer layer is then formed over the braid and extending beyond the distal end of the inner tubular member on to the mandrel. Preferably, the

soft outer layer is formed by first placing a preformed tube of the desired soft material over the assembly of the braid and inner tubular member and thereafter placing a heat shrink tube over the soft outer layer tubular material. The entire assembly is then heated to a temperature which melts the soft outer layer of material and which constricts the heat shrink tube over the assembly, thus applying pressure to the soft outer layer material. After cooling, the heat shrink tube can be cut from the catheter, and the distal end trimmed to a desired length. Optionally, a proximal connector can be attached to the proximal end of the catheter body.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a catheter constructed in accordance with the principles of the present invention, with portions broken away.

Fig. 2 is a detailed, elevational view of the distal end of the catheter of Fig. 1 taken at line 2-2.

DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides an improved construction for catheters of the type having an elongated catheter body with a central lumen extending from proximal end to a distal end thereof. Such constructions are particularly useful for forming very small diameter catheters, having outside diameters of 4 mm (12 F) preferably below 2.67 mm (8 F), and frequently as small as 1 mm (3 F), and below, such as those used in neurological diagnostic and interventional procedures. Such small catheters will also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like, for access to the small vasculature as necessary. Constructions of the present invention, however, are not limited to such small diameter catheters, and will be useful for larger diameter catheters as well, such as vascular guiding

catheters which may have outside diameters larger than 4 mm.

5 Catheters according to the present invention will comprise a catheter body having dimensions and a geometry selected for the intended use. The catheter body will typically have a length in the range from about 40 cm to 200 cm, usually having a length in the range from about 60 cm to 175 cm. The outside diameter of the catheter body will typically be in the range from about 0.33 mm (1 F) to 4 mm (12 F), usually being in the range from about 0.66 mm (2 F) to about 2.66 mm (8 F). The catheter body will define an inner lumen typically having a diameter in the range from about 0.1 mm to 3.6 mm, usually being in the range from about 0.3 mm to 2.5 mm, with catheters having larger outside diameters usually having larger lumen diameters. For the preferred microcatheters of the present invention, the catheter body will have a length in the range from about 80 cm to 150 cm, an outside diameter in the range from about 0.66 mm to 1.5 mm, and an inside diameter in the range from about 0.375 mm to 1.05 mm.

20 The catheter body will usually be straight along all or most of its length. By "straight" it is meant that the catheter body will assume a straight or linear configuration, when free from external bending forces. The catheter body, however, will be highly flexible so that it will be able to pass through the tortuous regions of a patient's vasculature, as described in more detail herein below. In some cases, the catheter bodies may have a shaped distal end including curves and bends which are selected to facilitate introduction and placement of the catheter (usually over a separate guide wire) in the vascular system. A particular geometry of curves and/or bends may be selected to accommodate the intended use of the catheter.

35 The catheter body will usually include at least two, and more usually three distinct regions, with each

region having a different construction resulting in different mechanical properties. A shaft region extends from the proximal end of the catheter body to a location spaced within 20 cm of the distal end of the catheter body, usually from 2 cm to 6 cm of the distal end. The shaft region will have the maximum reinforcement of the catheter body (including all three layers), thus having most column strength and hoop strength but the least flexibility. A transition region is located immediately on the distal side of the shaft region and extends to a location spaced within 10 cm of the distal end of the catheter body, usually from 1 cm to 3 cm of the distal end. The transition region will have an intermediate level reinforcement (including the inner tubular member and the soft outer layer, but lacking the braided reinforcement layer) together with intermediate levels of column strength, hoop strength, and flexibility. A distal region extends distally from the transition region, and is composed of a soft, unreinforced material. The distal region will generally be relatively short, typically having a length in the range from about 1 cm to 3 cm, and will have the greatest flexibility of the three regions of the catheter body.

In a first alternate embodiment, the braided reinforcement layer terminates at the distal end of the inner tubular member, with the soft outer layer extending distally from 1 cm to 10 cm, preferably from 1 to 3 cm. In a second alternate embodiment, the outer soft layer terminates at the distal end of the inner tubular member, with the braided reinforcement layer terminating proximally of both the outer layer and tubular member by a distance in the range from 1 cm to 10 cm, preferably from 1 cm to 3 cm. In both these embodiments, the catheter has two distinct regions with different mechanical properties.

As a consequence of the preferred fabrication technique, as described in more detail below, the

diameters of the transition region and the distal region of the catheter body may be somewhat smaller than that of the shaft region. While such a decrease in geometry in the distal direction may be advantageous, is not
5 essential for the catheters of the present invention. Thus, the present invention includes both catheters having uniform diameters along their entire length and catheters having diameters which decrease in the distal direction.

10 In a preferred construction, the catheter body of the present invention will consist essentially of three structural components. The first component is an inner tubular member which defines the inner lumen and provides a lubricious surface to receive the fluid or
15 device which is to be introduced to a target location within the vasculature or other body lumen. Typically, the inner tubular member will be a sleeve formed from a single material, preferably a lubricious polymer, such as a fluorocarbon (e.g., polytetrafluoroethylene (PTFE)), a
20 polyamide (e.g., nylon), a polyolefin, a polyimide, or the like. It would also be possible to form the inner tubular members as a laminate structure comprising a non-lubricious outer layer and an inner lubricious layer or coating.

25 The second structural component of the catheter body is a braided reinforcement layer comprising braided filaments formed directly over the inner tubular member using conventional braiding techniques. The braid
30 filaments will have a very small cross-sectional area while possessing sufficient tensile strength to undergo the braiding process. Preferably, the braid filaments will be composed of stainless steel, a shape memory alloy (e.g., Nitinol®), polymeric fibers, or the like.
35 Particularly preferred are stainless steel filaments having a rectangular cross-section with a width in the range from 0.001 inch to 0.01 inch, preferably being about 0.015 inch, and a thickness in the range from

0.0002 inch to 0.002 inch, preferably being about 0.001 inch. Such small filaments can be formed over the inner tubular member in a conventional one-over-one or two-over-two braid pattern, with the machine being
5 carefully adjusted to avoid excessive tensile forces on the filaments.

The third structural component of the catheter body is a soft outer layer which is formed over the braided reinforcement layer and which extends distally of
10 the distal end of the tubular member. The soft outer layer will cover the entire assembly of both the inner tubular member and the braided reinforcement layer, creating the three distinct regions discussed above in connection with the exemplary embodiment. The shaft
15 region will include all three structural components, i.e., the inner tubular member, the braided reinforcement layer formed over the inner tubular member, and the soft outer layer formed over the braided reinforcement layer. The transition region will include both the inner tubular
20 member and the soft outer layer, but will free from the braided reinforcement layer. In this way, the flexibility of the transition region is significantly improved, although the strength characteristics are reduced somewhat when compared to the shaft region. The
25 distal region will consist only of the soft outer layer. The soft outer layer will be formed so that it defines a distal lumen which is contiguous with the central lumen defined by the inner tubular member. Alternate embodiments lacking either of the two distal regions have
30 been described above.

The soft outer layer can be composed of a variety of materials, preferably being composed of a soft thermoplastic material having a hardness in the range from 30 A to 72 D. Exemplary materials include polyamide
35 polyether block copolymer (Pebax®), polyurethanes, silicone rubbers, nylons, polyethylenes, fluorinated hydrocarbon polymers, and the like.

Referring now to Figs. 1 and 2, a catheter 10 constructed in accordance with the principles of the present invention includes a catheter body 12 having a connector 14 at its proximal end. Connector 14 may be any standard medical interconnection device, such a luer fitting. The catheter body 12 includes a shaft region 16 which extends from the proximal connector 14 to a distal termination location, indicated by broken line 18. The transition region 20 extends from the termination 18 of the shaft region to a second termination location indicated by broken line 22. A distal region 24 extends from the termination 22 of the transition region 20 to a distal end 26 of the catheter body 12. The transition region 20 will thus have a length D_1 in the range from 0 cm to 10 cm, preferably from 1 cm to 10 cm, and more preferably from 1 cm to 3 cm and the distal region 24 will have a length D_2 in the range from 0 cm to 10 cm, preferably from 1 cm to 10 cm, and more preferably from 1 cm to 3 cm, as shown in Fig. 2.

The catheter body 12 includes an inner tubular member 30, typically comprising a PTFE tube. Braid structure 32 is then formed over the inner tubular member 30 from the proximal end thereof to near the termination location 18. The braid structure 32 will be square cut, as described in more detail hereinafter, so that it terminates cleanly at the desired termination location and is free from protrusions, burrs, and other discontinuities which could expose the patient to injury. A soft outer layer 34 extends from the proximal end of catheter body 16 to the distal end 26, covering both the inner tubular member 30 and the reinforcement braid 32.

According to a preferred fabrication method, the catheter body 12 may be formed by placing a selected length of PTFE or other tubing over an elongate mandrel. Usually, the mandrel will be coated with PTFE to facilitate introduction and removal of the mandrel to and from the structure being formed. The assembly of the

inner tubular member 30 over the mandrel is then introduced to a braiding machine, such as those available from Steeger, Germany; Wardwel, Massachusetts; and other commercial suppliers, where a conventional one-over-one or two-over-two braid pattern is formed. The pic and other characteristics of the braid will be selected to provide the desired stretch and flexibility for the shaft region. Usually, the pic will be in the range from 20 to 150 pics/inch, preferably from 60 to 100 pics/inch, and the pic may be constant over the entire length of the braided reinforcement layer or may be varied to increase flexibility at or near the distal end of the shaft region. In particular, the braid characteristics such as the pic, cross-sectional area, material strength, and the like, may be varied to provide increased flexibility at the distal end of the catheter body, typically over the distal 1 cm to 60 cm of the catheter body, usually over at least 5 cm, and more usually from 10 cm to 60 cm. The increased flexibility may be constant over the distal end, or may be progressive (i.e., becoming increasingly flexible near the distal end). The use of such non-uniform braid characteristics to enhance flexibility at the distal end of the catheter body is particularly useful when the inner tubular member, reinforcement layer, and soft outer layer are terminated within 1 cm of each other.

In a particular aspect of the fabrication technique of the present invention, the braid is formed over a length which is slightly greater than that desired in the final construction. After forming the braid, the braid will be slipped distally over the inner tubular member so that it extends beyond both the inner tubular member and the mandrel. The stainless steel braid material will then be heat annealed, typically by exposure to a flame or resistance heater, and will thereafter be transversely cut to provide a clean, square-cut distal end. After being cut, the braid is

then pulled proximally back over the mandrel and the inner tubular member 30, so that the distal termination 18 of the braid lies at the desired location.

5 The soft outer layer 34 is then formed over the assembly of the inner tubular member 30 and the braid 32 by placing a thermoplastic tube, typically a Pebax® tube, over the entire assembly so that a distal end of the tube extends distally of the distal end of inner tubular member 30. A heat shrink tube, such as a polyethylene or
10 fluoropolymer tube, is then placed over the soft thermoplastic, and the entire assembly placed in an oven and heated to a temperature sufficient to melt the thermoplastic and constrict the heat shrink tube over the melted thermoplastic. In this way, the thermoplastic
15 material is able to impregnate the braid 32 and is constricted over the mandrel to form a contiguous lumen, as best illustrated in Fig. 2. By carefully choosing the mandrel diameter to match that of the inner diameter of tubular member 30, a very smooth transition between the
20 lumen of inner tubular member 30 and that defined by the soft outer layer 26 can be obtained.

After cooling, the heat shrink tube can be cut from the catheter body assembly. The distal end of a soft outer layer can then be cut to its desired final
25 length. The proximal connector 14 can then be attached to the proximal end of the catheter body 12, although the connector is not an essential part of the present invention.

The catheter 10 just described can be further
30 modified for particular uses. For example, small perfusion ports or holes can be formed near the distal end of the catheter body in order to facilitate liquid perfusion, e.g., drug delivery, using the catheter. Additionally, coatings such as hydrophilic, anti-
35 thrombogenic, low-friction, hydrophobic, and other, coatings can be placed over the outer surface of the catheter body 12 in order to enhance its use for

particular applications. Additionally, the tip can be formed into a desired geometry, as described above, and the strength and flexibility characteristics of the shaft region can be further modified by appropriate
5 modification of the braid characteristics.

The catheter 10 can be further modified by providing radiopaque markers at one or more locations along its length. Such radiopaque markers can comprise metal rings, or can be defined by impregnating the soft
10 polymeric layer with appropriate radiopaque dyes. The provision of radiopaque markers is well known in the art and does not form a part of the present invention.

Although the foregoing invention has been described in detail for purposes of clarity of
15 understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A catheter comprising:

5 an inner tubular member having a proximal end,
a distal end, and a lumen extending from the proximal end
to the distal end;

a braided reinforcement layer disposed over the
inner tubular member and having a proximal end and a
distal end, wherein the distal end of the braided
10 reinforcement layer terminates at a distance in the range
from 0 cm to 10 cm proximally from the distal end of the
inner tubular member; and

a soft outer layer formed over the braided
reinforcement layer and extending distally of the distal
15 end of the inner tubular member by a distance in the
range from 0 cm to 10 cm.

2. A catheter as in claim 1, wherein the
braided reinforcement layer terminates from 1 cm to 10 cm
20 from the distal end of the inner tubular member and the
soft outer layer terminates from 1 cm to 10 cm from the
distal end of the inner tubular member, and wherein the
soft outer layer has a distal lumen contiguous with the
lumen of the inner tubular member.

25 3. A catheter as in claim 1, wherein the
braided reinforcement layer terminates at the distal end
of the inner tubular member and the soft outer layer
extends distally of the braided layer and inner tubular
30 member by a distance in the range from 1 cm to 10 cm, and
wherein the soft outer layer has a distal lumen
contiguous with the lumen of the inner tubular member.

35 4. A catheter as in claim 1, wherein the soft
outer layer terminates at the distal end of the inner
tubular member and the braided reinforcement layer

terminates from 1 cm to 10 cm from the distal ends of the soft outer layer and the inner tubular member.

5 5. A catheter as in claim 1, wherein the soft
outer layer and braided reinforcement layer terminate
within 1 cm of the inner tubular member and wherein the
braid characteristics of the braided reinforcement layer
are selected to increase flexibility within the distal 1
to 60 cm of the catheter body relative to a proximal
10 portion of the catheter body.

 6. A catheter as in claim 1, wherein the inner
tubular member is composed of a material selected from
the group consisting of fluorocarbons, polyamides,
15 polyolefins, and polyimides.

 7. A catheter as in claim 6, wherein the inner
tubular member is polytetrafluoroethylene.

20 8. A catheter as in claim 1, wherein the
braided reinforcement layer comprises at least one
stainless steel braid formed over the inner tubular
member.

25 9. A catheter as in claim 8, wherein the
distal end of the stainless steel braid has been annealed
and transversely cut to remove protrusions.

30 10. A catheter as in claim 1, wherein the soft
outer layer is composed of a material having a hardness
in the range from 30 A to 72 D.

35 11. A catheter as in claim 10, wherein the
material is selected from the group consisting of
polyether block copolymer, polyurethane, silicone rubber,
nylon, polyethylene, and fluorinated hydrocarbon
polymers.

12. A catheter as in claim 1, wherein the soft outer layer is impregnated into the braided reinforcement layer.

5 13. A catheter as in claim 1, further comprising a connection fitting at the proximal end of the inner tubular member, braided reinforcement layer, and soft outer layer.

10 14. A catheter body consisting essentially of an inner tubular member having a proximal end, a distal end, a lumen extending from the proximal end to the distal end, and having an inner diameter in the range from 0.33 mm to 4 mm;

15 a braided reinforcement layer disposed over the inner tubular member and having a proximal end and a distal end, wherein the distal end of the braided reinforcement layer terminates at a distance in the range from 1 cm to 10 cm proximally from the distal end of the
20 inner tubular member; and

a soft outer layer formed over the braided reinforcement layer and extending distally of the distal end of the inner tubular member by a distance in the range from 1 cm to 10 cm, wherein soft outer layer has a
25 distal lumen contiguous with the lumen of the inner tubular member and wherein the outer diameter of the soft outer layer is in the range from 0.1 mm to 3.6 mm.

30 15. A catheter body as in claim 14, having a length in the range from about 40 cm to 200 cm.

35 16. A catheter body as in claim 14, wherein the inner tubular member is composed of a material selected from the group consisting of fluorocarbons, polyamides, polyolefins, and polyimides.

17. A catheter body as in claim 16, wherein the inner tubular member is polytetrafluoroethylene.

5 18. A catheter body as in claim 14, wherein the braided reinforcement layer comprises at least one stainless steel braid formed over the inner tubular member.

10 19. A catheter body as in claim 18, wherein the distal end of the stainless steel braid has been annealed, and transversely cut to remove protrusions.

15 20. A catheter body as in claim 14, wherein the soft outer layer is composed of a material having a hardness in the range from 30 A to 72 D.

20 21. A catheter body as in claim 20, wherein the material is select from the group consisting of polyether block copolymer, polyurethane, silicone rubber, nylon, polyethylene, and fluoronated hydrocarbon polymers.

25 22. A catheter body as in claim 14, wherein the soft outer layer is impregnated into the braided reinforcement layer.

23. A method for fabricating a catheter, said method comprising:

30 providing an inner tubular member having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end;

forming a braid over the inner tubular member from the proximal end to a location spaced proximally from the distal end by a distance in the range from 0 cm to 10 cm; and

35 forming a soft outer layer over the inner tubular member and extending distally beyond the distal

end thereof by a distance in the range from 0 cm to 10 cm.

5 24. A method as in claim 23, wherein the inner tubular member is disposed over a mandrel which extends beyond the distal end of the inner tubular member.

10 25. A method as in claim 23, where a one-over-one stainless steel braid is formed over the inner tubular member.

15 26. A method as in claim 24, further comprising annealing a distal end of the braid and transversely cutting said distal end to remove protrusions.

20 27. A method as in claim 23, wherein the soft layer is formed by placing a thermoplastic tube over the braid, inner tubular member, and mandrel, and applying heat and pressure to melt the thermoplastic and impregnate the thermoplastic into the braid.

25 28. A method as in claim 23, wherein the inner tubular member is composed of a material selected from the group consisting of fluorocarbons, polyamides, polyolefins, and polyimides.

30 29. A method as in claim 28, wherein the inner tubular member is polytetrafluoroethylene.

35 30. A method as in claim 23, wherein the soft outer layer is composed of a material having a hardness in the range from 30 A to 72 D.

 31. A method as in claim 30, wherein the material is selected from the group consisting of

polyether block copolymer, polyurethane, silicone rubber, nylon, polyethylene, and fluoronated hydrocarbon polymers.

5 32. A method as in claim 23, further comprising attaching a connection fitting to the proximal ends of the inner tubular member, braided reinforcement layer, and soft outer layer.

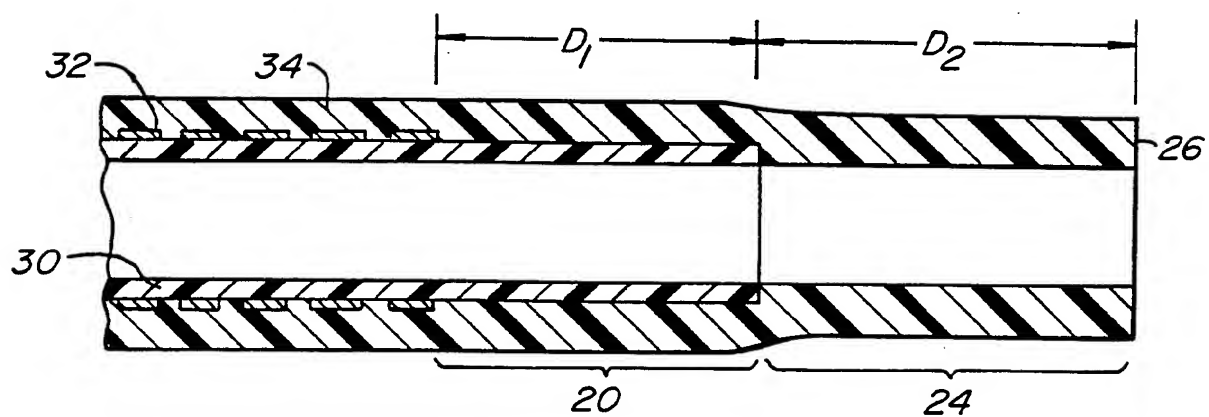
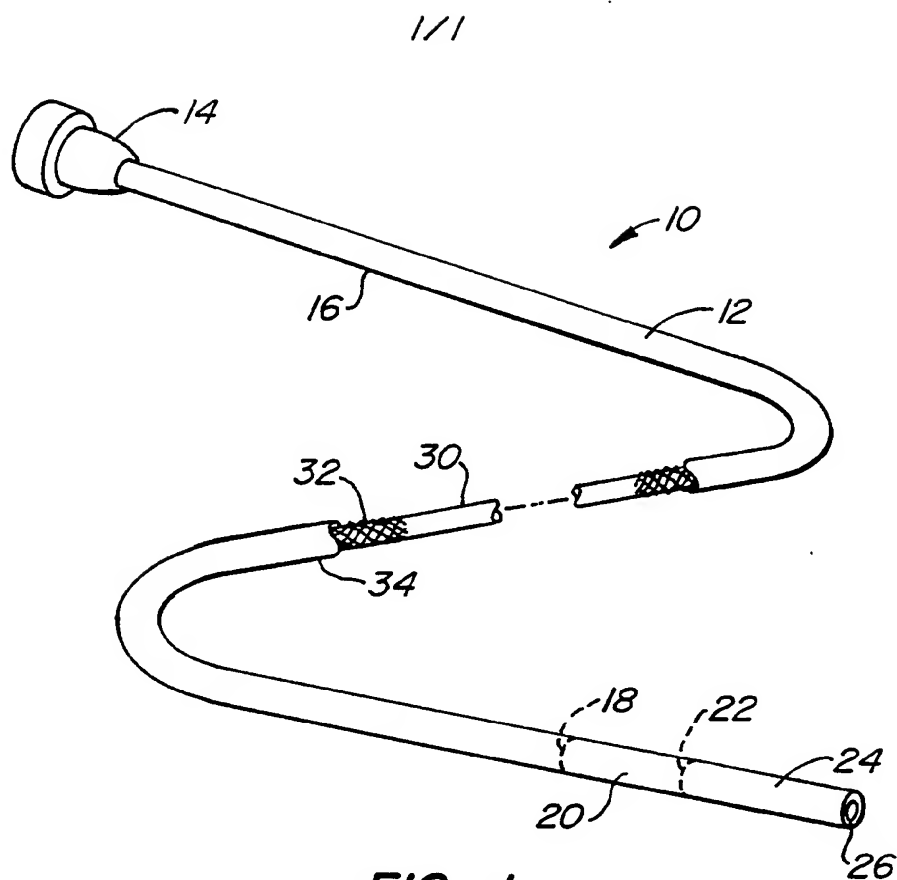
10 33. A method as in claim 23, wherein the braided reinforcement layer terminates from 1 cm to 10 cm from the distal end of the inner tubular member and the soft outer layer terminates from 1 cm to 10 cm from the distal end of the inner tubular member, and wherein the
15 soft outer layer has a distal lumen contiguous with the lumen of the inner tubular member.

 34. A catheter as in claim 23, wherein the braided reinforcement layer terminates at the distal end
20 of the inner tubular member and the soft outer layer extends distally of the braided layer and inner tubular member by a distance in the range from 1 cm to 10 cm, and wherein the soft outer layer has a distal lumen contiguous with the lumen of the inner tubular member.

25 35. A catheter as in claim 23, wherein the soft outer layer terminates at the distal end of the inner tubular member and the braided reinforcement layer terminates from 1 cm to 10 cm from the distal ends of the
30 soft outer layer and the inner tubular member.

 36. A catheter as in claim 23, wherein the soft outer layer and braided reinforcement layer
35 terminate within 1 cm of the inner tubular member and wherein the braid characteristics of the braided reinforcement layer are selected to increase flexibility

within the distal 1 to 60 cm of the catheter body
relative to a proximal portion of the catheter body.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13014

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00; F16L 11/00

US CL :138/124; 604/282

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/658; 138/123-125, 137-141, 143-145, 153; 604/264, 280-282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,863,442, (DEMELLO ET AL.), 05 September 1989. See entire document.	1, 2, 4-11, 13-21, 23, 24, 28-33, 35, 36
X --- Y	US, A, 5,221,270, (PARKER), 22 June 1993. See entire document.	1-24, 28-36 ----- 26, 27
Y	US, A, 5,254,107, (SOLTESZ), 19 October 1993. See entire document.	26
Y	US, A, 5,005,587, (SCOTT), 09 April 1991. See column 5, lines 45-56.	26
Y	US, A, 3,924,632, (COOK), 09 December 1975. See column 3, lines 55-70.	27

☐ Further documents are listed in the continuation of Box C.
☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
03 JANUARY 1995Date of mailing of the international search report
14 MAR 1995Name and mailing address of the ISA/US
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